TITLE 17 CALIFORNIA DEPARTMENT OF HEALTH SERVICES

ACTION: Notice of Proposed Rulemaking

SUBJECT: Reporting of Human Immunodeficiency Virus (HIV) (R-19-00)

PUBLIC PROCEEDINGS: Notice is hereby given that the California Department of Health Services will conduct a public hearing commencing at 10 a.m. on May 16, 2001 in the auditorium at 714 P Street, Sacramento, CA, during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions relevant to the action described in this notice. Any written statements, arguments or contentions must be received by the Office of Regulations, Department of Health Services, 714 P Street, Room 1000, P.O. Box 942732, Sacramento, CA 94234-7320, by 5 p.m. on May 21, 2001, which is hereby designated as the close of the written comment period. It is requested but not required that written statements, arguments or contentions sent by mail or hand-delivered be submitted in triplicate.

Comments by FAX (916-657-1459) or email (regulation@dhs.ca.gov) must be received before 5:00 p.m. on the last day of the public comment period. All comments, including email or fax transmissions, should include the author’s name and U.S. Postal Service mailing address in order for the Department to provide copies of any notices for proposed changes in the regulation text on which additional comments may be solicited.

CONTACTS: Inquiries concerning the action described in this notice may be directed to Barbara Gallaway, R.N., M.S.N. of the Office of Regulations at (916) 657-3197, or to the designated backup contact person, Linda Tutor, at (916) 654-0381. Inquiries regarding the substance of the proposed regulations may be directed to Jim Creeger of Office of AIDS at (916) 322-1065. In any such inquiries, please identify the action by using the Department regulation control number **R-19-00**.

Persons wishing to use the California Relay Service may do so at no cost. The telephone numbers for accessing this service are: 1-800-735-2929, if you have a TDD; or 1-800-735-2922, if you do not have a TDD.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW:

Health and Safety Code, Section 120125 requires the California Department of Health Services (Department) to examine the causes of communicable disease occurring or likely to occur in the state, and Health and Safety Code, Section 120130 authorizes the Department to establish a list of reportable communicable or non-communicable diseases. Health and Safety Code, Section 120140 authorizes the Department, upon being informed by a Health Officer of a contagious, infectious or communicable disease, to ascertain the nature of the disease and prevent its spread. Special reporting

protocols and epidemiological investigations are required when these diseases or conditions are identified.

An Acquired Immunodeficiency Syndrome (AIDS) diagnosis constitutes the presence of specified medical conditions in conjunction with Human Immunodeficiency Virus (HIV) infection. California Code of Regulations (CCR), Title 17, Division 1, Chapter 4, Subchapter 1, Article 1, Section 2500, subsection (b) requires health care providers to report specified conditions, listed in subsection (j), to the local Health Officer for the jurisdiction where the patient resides. Section 2502, subsection (b) specifies that the local Health Officer shall report these cases to the State Department of Health.

HIV, the causative agent of AIDS, is not included on the list of reportable conditions. To ensure the public health, general welfare, and safety of the people of the State of California, the Department proposes to adopt Article 3.5, Sections 2641.5 through 2645 into the CCR, Title 17, Division 1, Chapter 4, Subchapter 1, which will mandate HIV reporting in California.

HIV is transmitted from one person to another through a variety of ways and causes AIDS, a deadly disease. An early accounting of the number and geographic location of those infected with HIV in California would help health officials monitor the epidemic, target efforts to prevent further transmission of the virus, and assist with allocating resources for care and treatment of HIV disease. Medical, public health, and HIV/AIDS experts broadly support the development of HIV surveillance systems to more accurately track the epidemic. This proposal would require HIV reporting by a non-name code to track trends in the HIV epidemic while protecting the privacy of HIV-infected individuals.

Under CCR, Title 17, Division 1, Chapter 4, Subchapter 1, Article 3.5, health care providers and laboratories will be required to report confirmed HIV tests to the local Health Officer of the jurisdiction where the health care provider facility is located. For the purpose of this Article, health care provider is defined as an individual authorized by his or her scope of practice as specified in the Business and Professions Code, Division 2 (Healing Arts), to (a) submit a human biological specimen to a laboratory for a test to detect the presence of HIV, a component of HIV, or antibodies or antigens to HIV, and (b) receive laboratory test results. This includes designees authorized by and acting under the general supervision of a licensed physician and surgeon, or persons working in publicly-funded confidential counseling and testing programs acting under the general supervision of, and following the protocols approved by, the Health Officer for the local health department.

Information provided by the laboratory to the local Health Officer shall include the confirmed HIV test result; a laboratory-generated report number; the first and third letters of the patient's last name; the complete date of birth and gender of the patient; the name, address, and telephone number of the health care provider and facility that submitted the biological specimen to the laboratory; the date the biological specimen was tested by the laboratory; and the name, address, and telephone number of the

laboratory.

Reporting by the health care provider shall be accomplished by the development of a non-name code for the HIV-infected patient. Upon creation of the code, the health care provider shall complete and submit to the local health department either the California Department of Health Services Adult or Pediatric HIV/AIDS Confidential Case Report form, numbered DHS 2001A (revised 1/01) and DHS 2001B (revised 1/01). Form DHS 2001A is used to report individuals 13 years of age and older at the time of diagnosis, and DHS 2001B is used for those under 13 years of age. Both forms are modifications of Centers for Disease Control and Prevention (CDC) forms used for the reporting of AIDS and HIV throughout the United States. Forms DHS 2001A and DHS 2001B contain the data fields for epidemiologic information requested by CDC, and are incorporated by reference in their entirety in this document.

These regulations establish requirements for, and incorporate by reference the following forms:

1. "HIV Antibody Test," DHS 8257A, dated (3/01);
2. "California Department of Health Services Adult HIV/AIDS Confidential Case Report," DHS 2001A, dated (1/01);
3. "California Department of Health Services Pediatric HIV/AIDS Confidential Case Report," DHS 2001B, dated (1/01);
4. "Instructions for Soundexing," DHS 2001SC, dated (3/01).

Currently, there are no existing federal regulations or statutes applicable to this proposed action. However, in the December 10, 1999 issue of the CDC Morbidity and Mortality Weekly Report (Vol. 48, No. RR-13), CDC released a recommendation that all states and territories conduct HIV case surveillance as an extension of their current AIDS surveillance activities. Although the CDC request is not a mandate, future federal surveillance and Ryan White Comprehensive AIDS Resources Emergency (CARE) Act funds will be contingent upon the number of estimated living HIV and AIDS cases in each state. As of December 2000, 47 states have implemented a system for reporting HIV infection. Of these, 34 states report HIV-infected persons by name, seven states report by a non-name code, three states report by a hybrid name/code system, and four states report with no identifying information.

This regulation package proposes the adoption of Sections 2641.5, 2641.10, 2641.15, 2641.20, 2641.25, 2641.30, 2641.35, 2641.40, 2641.45, 2641.50, 2641.55, 2641.60, 2641.65, 2641.70, 2641.75, 2641.80, 2641.85, 2641.90, 2643.5, 2643.10, 2643.15, 2643.20 and 2645.

AUTHORITY: Sections 1224 and 1288, Business and Professions Code; and Sections 100180, 100275, 101160, 120125, 120130 and 120140, Health and Safety Code.

REFERENCE: Sections 1202, 1202.5, 1206, 1206.5, 1209, 1220, 1241, 1265, 1281, 1285 and 1288, Business and Professions Code; and Sections 100180, 101150, 101160, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

FISCAL IMPACT ESTIMATE:

A. Fiscal Effect on Local Government: The fiscal impact cannot be calculated until after these regulations are in effect. The impact can only be determined by the number of HIV case reports, the level of completeness of the case report forms submitted, the level of assistance required by providers, and the time required to unduplicate HIV reports. It is estimated that the local health department staff would require approximately five minutes to verify completion of each report and forward unduplicated reports assuming all data is complete.

B. Fiscal Effect on State Government: $1,431,000 General Funds have been included in Item 4260-111-0001, Budget Act of 2000 to assist local health jurisdictions to reasonably comply with this mandate.

C. Fiscal Effect on Federal Funding of State Programs: The Centers for Disease Control has contributed $500,000 to the State Office of AIDS to fund evaluation studies on the effectiveness of different types of coded reporting. If California cannot implement HIV reporting, two annual federal grant awards may be reduced.

D. All cost impacts, known to the Department at the time the notice of proposed action was submitted to the Office of Administrative Law, that a representative private person or business would necessarily incur in reasonable compliance with the proposed action:

1. It is estimated that laboratory personnel would require no more than five minutes to report the laboratory results to the health care provider and the local Health Officer. The impact on laboratories can only be determined by the number of confirmed tests and the personnel costs of the reporting staff.

2. It is estimated that health care providers would require an average of ten minutes to collect and report the required information. The impact on health care providers can only be determined by the actual number of patients confirmed and the manner in which the provider reports HIV cases.

3. The Department is not aware of any cost impacts that a representative private person would necessarily incur in reasonable compliance with the proposed action.

E. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None known.

DETERMINATIONS: The Department has determined that the regulations would impose a mandate on local agencies that is reimbursable according to Section 6 of Article XIIIB of the California Constitution, and Part 7 (commencing with Section 17500) of Division 4 of the Government Code. Funds in the amount of $1,431,000 have been approved and made available in the FY 2000-2001 State baseline budget to help local health departments reasonably comply with this mandate.

The Department has made an initial determination that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The Department has determined that the regulations would not significantly affect the following:

(1) The creation or elimination of jobs within the State of California.

(2) The creation of new businesses or the elimination of existing businesses within the State of California.

(3) The expansion of businesses currently doing business within the State of California.

The Department has determined that the regulations would affect small business. Currently, laboratories report all test results to the submitting health care provider and, by law, both laboratories and health care providers report specified communicable and non-communicable diseases to the local Health Officer. These regulations will add confirmed HIV test results to the list of conditions reportable to the local Health Officer by both laboratories and health care providers.

The Department has determined that the regulations will have no impact on housing costs.

The Department finds that reports required of health care providers and laboratories by this proposal are necessary for the protection of the health, safety and welfare of Californians.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS: The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. A copy of the initial statement of reasons and a copy of the text of the proposed regulations are available upon request by writing to the Office of Regulations at the address noted above, which address will also be the location of public records, including reports, documentation, and other material related to the proposed regulations (the public rulemaking file). Additionally, a copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations at the address noted above. Materials

regarding the proposed regulations that are available via the Internet may be accessed at http://www.dhs.ca.gov/regulation/.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

ADDITIONAL STATEMENTS AND COMMENTS: In accordance with Government Code Section 11346.5(a)(13) the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

INITIAL STATEMENT OF REASONS

The purpose of conducting public health surveillance is to determine ongoing patterns of disease occurrence and the potential for disease in a population. Agencies use surveillance data to describe and monitor health events in their jurisdictions; set priorities; and assist in the planning, implementation and evaluation of public health interventions and programs. The most well established systems for surveillance are usually those that monitor the occurrence of communicable diseases through required reporting by health professionals such as physicians and laboratories.

The use of health-related information for public health purposes is critically important for preserving, monitoring and improving population-based health as well as the personal health of individuals. Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) surveillance information serves as a scientific basis for programs and policies aimed at preventing and reducing the incidence of HIV infection, HIV-related conditions and death.

Health and Safety Code, Section 120125 requires the California Department of Health Services (Department) to examine the causes of communicable disease occurring or likely to occur in the state. Health and Safety Code, Section 120130 authorizes the Department to establish a list of reportable communicable or non-communicable diseases and requires that the local Health Officer report those diseases to the Department. Health and Safety Code, Section 120140 authorizes the Department, upon being informed by a Health Officer of a contagious, infectious or communicable disease, to ascertain the nature of the disease and prevent its spread. To accomplish this, California Code of Regulations (CCR), Title 17, Division 1, Chapter 4, Subchapter 1, Article 1, Section 2500, subsection (b) directs health care providers to report diseases or conditions listed in subsection (j) to the local Health Officer. AIDS is one of these conditions, but HIV, the cause of AIDS, is not. The Department proposes to adopt Article 3.5, Sections 2641.5 through 2645 to the CCR, Title 17, Division 1, Chapter 4, Subchapter 1, which will mandate the reporting of most cases of HIV infection in California.

AIDS is a devastating illness that has killed over 70,000 people in California and millions of people throughout the world. AIDS is caused by HIV, a retrovirus that infects and kills certain infection-fighting cells in the body. When these cells, called CD4+ T-lymphocytes (T-cells), are reduced in large numbers, certain opportunistic infections and/or cancers develop, causing severe illnesses that may ultimately lead to death. Typically, any of these infections or cancers, or a low CD4+ T-cell count, in conjunction with a positive test for HIV, defines the clinical diagnosis of AIDS. An individual may be infected with HIV for as long as 10 years before opportunistic infections and/or cancers begin invading the body, or before the effects of these conditions can be observed. Throughout this entire period, the individual is capable of infecting others with HIV.

Since the AIDS epidemic was first identified in the United States in 1981, population-based AIDS surveillance (reporting of AIDS cases and their characteristics to public

health authorities for epidemiologic analysis) has been used to track the epidemic. Over 753,000 AIDS cases have been reported nationwide and, as of January 2001, 120,076 cases have been reported in California.

In 1996, national AIDS incidence and AIDS deaths declined for the first time during the epidemic. Declines have been primarily attributed to the use of combination antiretroviral therapies, which delay the progression from HIV infection to an AIDS diagnosis and death. Prior to the emergence of effective drug treatment therapies for HIV infection, AIDS surveillance data was a reasonable, although not timely, method for detecting changing patterns of HIV transmission. AIDS surveillance data are currently used as a contributing factor to allocate federal resources for AIDS-related treatment and care services, and as the epidemiologic basis for planning local HIV prevention and care services. Changes in the medical standard of care for HIV-infected individuals have produced a delayed progression from HIV infection to AIDS diagnosis. As a result, AIDS surveillance statistics alone no longer reliably reflect the course of the epidemic or trends in HIV transmission, and are less useful for targeting HIV education, prevention and care efforts.

In California, individuals diagnosed with AIDS are reported by name to the public health authorities. AIDS case information for the state is maintained in the California Department of Health Services, Office of AIDS HIV/AIDS Case Registry, a confidential, central registry of demographic and clinical information. Registry staff collects data from local health departments throughout the state and forwards the information, without personal identifiers, to the federal Centers for Disease Control and Prevention (CDC) as part of national AIDS surveillance.

Although HIV reporting is mandated in 47 other states, HIV infection without an AIDS diagnosis is currently not reportable in California. Lack of this information limits the state's ability to perform epidemiologic analysis to help monitor and project the extent of the HIV/AIDS epidemic, plan prevention strategies, and identify at-risk populations. In response to the delayed progression to AIDS and the information needs of public health and other policymakers, CDC recommended that all states extend their AIDS case surveillance activities to include HIV case surveillance (CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome. MMWR 1999; 48 [No. RR-13]). The Department, in concurrence with the CDC recommendation for states to conduct HIV surveillance, proposes to adopt Article 3.5, Sections 2641.5 through 2645 into the CCR, Title 17, Division 1, Chapter 4, Subchapter 1.

According to the CDC, states that report both HIV infection and AIDS have documented that the prevalence of those living with HIV infection, combined with those living with an AIDS diagnosis, provides a more realistic and useful estimate of the resources needed for patient care and services than does AIDS prevalence alone. The combination of HIV and AIDS surveillance data provides a minimum estimate of individuals known to be HIV-infected. These data do not represent total prevalence of HIV infection, for not all HIV-infected people seek testing. Others may test with home collection kits and

many test at anonymous testing sites, which are not included in surveillance data. HIV case surveillance characterizes HIV-infected populations including persons with evidence of recent HIV infection such as infants, adolescents and young adults. Statewide reporting of HIV infection in California will provide a strong basis for prioritizing services for persons and communities in greatest need; setting evidence-based prevention priorities; understanding how prevention strategies influence disease trends; estimating future resource needs; comparing the allocation of funds with the distribution of the epidemic; and evaluating the effectiveness of public health prevention and treatment recommendations.

The Department considered and rejected four alternatives to HIV reporting by non-name code: reporting by name; reporting by a hybrid of name and code; reporting without the use of any identifier; and no reporting. (1) HIV reporting by name is contrary to current California law. Reporting by name in California has received broad opposition from AIDS community advocates, AIDS service providers and people living with HIV/AIDS. Legislation proposed in California for HIV reporting by name has died in session. (2) A hybrid system of HIV reporting entails the release of an HIV-infected individual's name to the local health department as part of the HIV case report submitted by the health care provider. In a hybrid system, the local health department converts the name to a code and then destroys evidence of the name. This method of HIV reporting simplifies the reporting process for health care providers and enables local health departments to easily unduplicate HIV case reports. However, as in the first alternative, reporting HIV infection by name is against the law in California. (3) To report HIV infection without the use of any identifier impedes the ability to unduplicate HIV case reports and does allow for the collection of accurate demographic data. This type of reporting defeats the purpose of public health surveillance and would hinder California's compliance with the CDC HIV reporting guidelines. (4) No reporting of HIV infection would continue to deny California the opportunity to monitor the disease; appropriately plan, implement and evaluate public health interventions and programs; enhance efforts to prevent HIV transmission; and more appropriately target funding for HIV education and prevention, early intervention and treatment and care services. In the near future, the federal Ryan White Comprehensive AIDS Resources Emergency (CARE) Act funding will be based on the number of estimated living HIV and AIDS cases, rather than estimated living AIDS cases alone. Without an accurate and efficient system to report HIV infection, California will not be competitive with other states, and the state's CARE Act funding will be drastically reduced.

California's proposed HIV case surveillance system would report HIV infection using a non-name code. The non-name code shall be composed of a number of elements used together to establish the 'uniqueness' of the code while not readily identifying the individual. Components shall consist of the HIV-infected individual's Soundex code (a phonetic, alphanumeric code of the last name), complete birth date, gender and the last four digits of the Social Security Number.

The Department completed a survey to verify that the proposed components of the non-name code are consistent with the seven other states that report HIV infection in this

manner. Comparing California's proposed code with other non-name systems, it was determined that six states use some form of the HIV-infected individual's name and at least a portion of the birth date; four states include gender as part of their code. Six states collect the last four digits of the Social Security Number. Five states include the last four digits of the Social Security Number as part of their non-name code and one state uses the four digits only in the event of duplicate HIV case reports. Although none of the seven surveyed states had a coding system identical to California's proposal, five states had at least three elements that were equivalent. California has a substantially larger caseload compared to other states; therefore, the non-name code was designed to minimize the possibility of duplicate HIV reports.

In California, individuals may choose to be tested for HIV anonymously or confidentially. In accordance with Health and Safety Code Sections 120890-120895**,** anonymous testing is available at Alternative Testing Sites (ATS) administered by county health departments. Anonymous testing is also available in some clinical settings other than an ATS, such as some family planning, sexually transmitted disease and drug treatment clinics. Anonymous HIV testing maintains the anonymity of the patient. In contrast to anonymous testing, public health programs that offer confidential HIV testing link the patient to the test result in a restricted manner that protects patient confidentiality. Confirmed HIV test results for patients of an ATS or other anonymous HIV testing program, a blood bank, or participants of a blinded and/or unlinked seroprevalence study will not be included in California's HIV reporting system.

The proposed system of HIV reporting by non-name code is designed to track trends in the HIV epidemic while protecting the privacy of those who receive a confirmed HIV test result. The reporting process involves five separate parties: the health care provider who orders the test, the laboratory that performs the test, the local health department, the California Department of Health Services, Office of AIDS and the CDC. The local health department, the State Office of AIDS and the CDC will not have a record of the name of the HIV-infected individual, only the case report with the non-name code.

An AIDS diagnosis is determined and reported by a medical doctor and consists of the presence of HIV infection in conjunction with one or more specified clinical manifestations. In comparison, HIV infection is determined solely by the results of an HIV-associated test. HIV-associated tests are conducted by laboratories; therefore these facilities will be a vital link in the HIV reporting system. These regulations mandate laboratory reporting of confirmed HIV tests and correspond with current law that requires laboratories to report certain communicable diseases to public health authorities. Laboratory reporting of HIV infection to the local health department will serve as a control for determining the total number of confirmed HIV tests in a jurisdiction, as well as the location of the health care provider that originates the test (for follow-up purposes).

Confirmed HIV tests (reported by laboratories) and HIV case reports (submitted by health care providers) will be matched a number of times throughout the reporting process to ensure that duplicate reports are discovered and eliminated. The local

health department surveillance staff shall perform the first match by comparing the reported laboratory test result to the local HIV/AIDS database to determine if an HIV case report already exists. The second match, also performed by the local health department, matches unduplicated laboratory test results to new HIV case reports submitted by health care providers. The local health department will forward new HIV case reports that match reported confirmed test results to the California Department of Health Services, Office of AIDS, HIV/AIDS Case Registry. The State Office of AIDS HIV/AIDS Case Registry staff will match the report to the existing statewide database to determine if the HIV-infected individual has been reported from another health jurisdiction. If duplicate reports from differing jurisdictions are discovered, Registry staff will contact the two jurisdictions and a determination will be made by the two local health departments as to where the individual was living at the time of the first confirmation of HIV infection.

Local health departments and the State Office of AIDS will securely store HIV case report data in a manner similar to AIDS case reports. AIDS data is currently stored in a computer database secured and isolated from outside contact, and paper files are in a locked file within a secured area.

The State Office of AIDS plans to conduct pre- and post-implementation evaluation to determine the reliability of the HIV reporting system in California. Minimum HIV reporting performance standards released by CDC state that evaluation studies should demonstrate that reporting of HIV cases is complete ($\geq$ 85% of the total potential HIV cases to be reported) as well as timely ($\geq$ 66% of all possible HIV cases reported within six months of diagnosis). Additionally, evaluation of the system should result in $\leq$5% duplicate case reports and $\leq$ 5% incorrectly matched case reports. The State Office of AIDS has made the initial determination that the proposed elements of the non-name code (Soundex code, patient date of birth, patient gender, last four digits of patient Social Security Number) are crucial components for correctly matching and unduplicating HIV case reports and meeting the CDC minimum performance standards.

Pre-implementation evaluation will include the HIV Testing Survey (HITS) as well as a laboratory survey. HITS was developed by the CDC to assess why persons at risk for HIV seek, delay or avoid HIV testing and what factors influence their decisions. During the spring of 2001, the counties of Sacramento, San Diego and Alameda will participate in the third national survey. This HITS will provide valuable data on HIV testing patterns for men who have sex with men (recruited from gay bars), high risk heterosexuals (attending sexually transmitted disease clinics), and street-recruited injection drug users. HITS will also assess awareness of the proposed state policy for HIV surveillance and will evaluate HIV testing patterns among persons at risk for HIV.

A survey of California laboratories will determine the relative proportion of HIV tests run by each laboratory. Seropositivity rates and the availability of basic data for notification of confirmed HIV test results for patients of private versus public test sites will also be examined. A standardized questionnaire will be sent to directors of all laboratories licensed to conduct HIV antibody testing in California.

Post-implementation evaluation activities include:

- The creation of a non-name code for each name-based living AIDS case in the State HIV/AIDS Case Registry. The purpose of this activity is to match each HIV case report against the AIDS Registry to identify duplicated reports. Once matched, the HIV/AIDS Registry staff will create an HIV Registry of non-AIDS HIV infections for every case not listed in the AIDS Registry.

- An evaluation of the non-name HIV reporting system focused on the sensitivity and specificity of the code. The State Office of AIDS HIV/AIDS Case Registry will develop a separate database to assess the sensitivity and specificity of the non-name code. This database will contain the non-name code as well as individual elements from the HIV case report form. All HIV case reports will be entered into the HIV/AIDS Case Registry database upon receipt and prior to any follow-up by State Office of AIDS surveillance staff.

- An evaluation of the completeness of the reporting system using capture and recapture methodology with hospital discharge data, Medi-Cal data, AIDS Drug Assistance Program data and other databases to be identified. These secondary data sources will provide a valuable comparison group to assess the completeness of reporting.

- On-going analysis of HIV reporting data to assess the completeness of the non-name code. Analysis will determine the number and percentage of HIV case reports that: 1) have missing data in the component parts of the non-name code (e.g. when only three of the four Social Security Numbers are provided); 2) are submitted with the entire non-name code; and 3) have missing data for one or more elements of the non-name code (e.g. if the code does not include Soundex or Soundex as well as gender).

- On-going evaluation of the timeliness of HIV reporting. All new HIV cases will be evaluated from the time the HIV infection is confirmed by the laboratory to the time the case is reported to CDC. The interval between the HIV test date and the date the case is entered into the HIV/AIDS Reporting System (HARS) system by either the local health department or the State Office of AIDS will also be considered.

- Analysis of confidential and anonymous testing patterns, before and after the implementation of the non-name reporting system in California, to determine the possible impact of HIV reporting.

PROPOSED REGULATIONS

ADOPTION OF ARTICLE 3.5. Reporting of Human Immunodeficiency Virus (HIV) Infection

SUB-ARTICLE 1 DEFINITIONS

SECTION 2641.5 ALTERNATIVE TESTING SITE.

"Alternative Testing Site" (ATS) means an anonymous HIV testing site funded by the California Department of Health Services, administered by a county health department and operated pursuant to Health and Safety Code, Sections 120890-120895.

The intent of an ATS is to create a substitute location for individuals who, in the past, may have utilized plasma centers or blood banks to ascertain their HIV status. HIV tests at these sites are free and the client's anonymity is maintained by use of a number that corresponds to the biological specimen and the HIV test result. As statutorily mandated, an ATS does not collect any information that links a person's identity to the test request or the result. Confirmed HIV tests for ATS patients are not included in California's HIV reporting system because the lack of patient information creates an inability for an ATS or a laboratory to follow the reporting mandates of these proposed regulations. The definition helps to clarify for health care providers and laboratories that some confirmed HIV test results are not to be reported to the Health Officer.

SECTION 2641.10. ANONYMOUS COUNSELING AND TESTING PROGRAM.

"Anonymous Counseling and Testing Program" means a program offering HIV counseling and testing while maintaining the anonymity of the patient.

This definition helps to clarify that some confirmed HIV test results are not to be reported to the Health Officer. Anonymous Counseling and Testing Programs differ from an Alternative Testing Site in that they are not statutorily mandated and are not solely administered by a county health department. Anonymous Counseling and Testing Programs may be located in family planning, sexually transmitted disease and drug treatment centers. The client's anonymity is maintained by the use of a number that corresponds to the biological specimen and the HIV test result. Confirmed HIV tests for patients of Anonymous Counseling and Testing Programs are not included in California's HIV reporting system because the lack of patient information creates an inability for the program or a laboratory to follow the reporting mandates of these proposed regulations.

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SECTION 2641.15. ANONYMOUS HIV TEST

"Anonymous HIV Test" means an HIV test that maintains the anonymity of the patient.

Patients who wish to anonymously test for HIV infection must utilize the services of either an Alternative Testing Site or an Anonymous Counseling and Testing Program. Confirmed HIV test results for patients who test anonymously are not included in California's HIV reporting system because the lack of patient information creates an inability for laboratories or health care providers to follow the reporting mandates of these proposed regulations. This definition is necessary in order to clarify the difference between an anonymous HIV test and a confidential HIV test, and therefore which confirmed HIV test results are to be reported.

SECTION 2641.20. BIOLOGICAL SPECIMEN.

"Biological specimen" means any material that is derived from the human body.

This matches the definition in Business and Professions Code, Section 1206 (a) (1). Health care providers will obtain a biological specimen from patients who will be tested for HIV infection, and will forward the biological specimen to the laboratory for analysis.

SECTION 2641.25. CONFIDENTIAL HIV TEST.

"Confidential HIV Test" means an HIV test that links the test results to the patient in a restricted manner to protect against unauthorized disclosure of the identity of the patient.

Confirmed HIV test results for patients who test confidentially are included in California's HIV reporting system. Patients of confidential counseling and testing programs are given a unique eight-digit DHS Client Number when they request testing services. Although the program may collect the patient's name and other identifying information, the laboratory requisition slip, the biological specimen and the HIV test results are only marked with the number. This assists in maintaining patient confidentiality. The definition of a confidential HIV test is necessary as part of the proposed regulations to help clarify which confirmed HIV test results are to be reported by laboratories and health care providers to the Health Officer.

SECTION 2641.30. CONFIRMED HIV TEST.

"Confirmed HIV test" means the presence of HIV infection as determined by any clinical laboratory test or examination used to detect the presence of HIV, a component of HIV, or antibodies or antigens to HIV, including the HIV antibody (HIV-Ab), HIV p-24 antigen, Western blot (Wb), Immunofluorescent assay (IFA), viral load and virus isolation test.

A variety of clinical laboratory testing methods may be used to determine the presence of HIV infection for an individual. During the course of development of the HIV reporting regulations, the Office of AIDS met with representatives from clinical and public health laboratories. Since laboratories perform a wide variety of tests and examinations on a daily basis, the representatives requested that the HIV reporting regulations specify which confirmed HIV tests should be reported by laboratories to the local Health Officer.

SECTION 2641.35. DEPARTMENT.

“Department” means the California Department of Health Services, Office of AIDS.

As statutorily mandated in California Health and Safety Code, Section 100119, the Office of AIDS is the lead agency responsible for coordinating state programs, services, and activities relating to HIV/AIDS.

SECTION 2641.40. DHS CLIENT NUMBER.

“DHS Client Number” means a unique eight-digit number created by the California Department of Health Services and assigned to the patient by a publicly-funded confidential counseling and testing program.

Although the patient’s name and other identifying information is kept on file by the confidential counseling and testing program, the laboratory requisition slip, the biological specimen and the HIV test results contain the DHS Client Number rather than the patient’s name. This assists in maintaining patient confidentiality. The DHS Client Number is included on the laboratory report as well as the HIV/AIDS Case Report form, both which are submitted to the local Health Officer. This number is used by the counseling and testing program to match laboratory reports with the patient file and by the local Health Officer to match and unduplicate reports of confirmed HIV test results. The eight-digit DHS Client number used for HIV testing is assigned to the patient by the publicly-funded confidential counseling and testing program. The number has no correlation to a patient’s DHS Medi-Cal number, DHS California Children Services number, or any other previously assigned number used for DHS program services.

SECTION 2641.45. HEALTH CARE PROVIDER.

“Health care provider” means an individual authorized by his or her scope of practice as specified in the Business and Professions Code, Division 2 (Healing Arts), to (a) submit a human biological specimen to a laboratory for a test to detect the presence of HIV, a component of HIV, or antibodies or antigens to HIV, and (b) receive laboratory test results. This includes designees who are persons authorized by and acting under the general supervision of a licensed physician and surgeon, or persons working in publicly-funded confidential counseling and testing programs acting under the general supervision of, and following the protocols approved by, the Health Officer for the local health department.

Health care providers are a vital component of HIV reporting. They will submit biological specimens to laboratories for testing, will create a non-name code for each individual with a confirmed HIV test and will report those individuals to the Health Officer. Although the term “health care provider” is currently found in Title 17, Article 1, Section 2500, the definition was not appropriate for use in the HIV reporting regulations because it does not encompass the many publicly-funded counseling and testing programs that

provide HIV testing services for their patients. Additionally, the definition in Section 2500 includes professions that do not perform HIV testing for humans (for example a veterinarian). Therefore, the term “health care provider” was redefined for interpretation and use in the proposed new Article.

SECTION 2641.50. HEALTH OFFICER AND LOCAL HEALTH OFFICER.

“Health Officer and Local Health Officer” means the officer appointed by the local governing body (county, city, and district) as identified in Section 2500.

The Health Officer has multiple functions in the HIV reporting system. He or she has oversight responsibility for public health programs that provide services within his or her local health jurisdiction. Persons working in publicly-funded confidential counseling and testing programs act under the general supervision of, and follow the protocols approved by the Health Officer. Health Officers receive laboratory reports of confirmed HIV tests as well as HIV/AIDS Case Report forms submitted by health care providers. It is the responsibility of the Health Officer or his or her designee to match and unduplicate all reported confirmed HIV tests and HIV/AIDS Case Reports and submit unduplicated reports to the Department.

SECTION 2641.55. HIV/AIDS CASE REPORT.

“HIV/AIDS Case Report” means California Department of Health Services Adult or Pediatric HIV/AIDS Confidential Case Report form (DHS 2001A or 2001B, revised 1/01), hereby incorporated by reference in this Article and available from the local health department or the California Department of Health Services, Office of AIDS.

The health care provider completes an HIV/AIDS Case Report form when reporting a confirmed HIV test to the local Health Officer. The HIV/AIDS Case Report forms are used to reporting HIV infection as well as an AIDS diagnosis, which provides continuity in monitoring HIV disease. Several fields within the HIV/AIDS Case Report form are used solely for reporting AIDS cases. The form contains the data fields necessary to provide sufficient epidemiologic data for the Department and CDC.

SECTION 2641.60. LABORATORY.

“Laboratory” means a ‘clinical laboratory,’ a ‘physician office laboratory,’ or a ‘public health laboratory,’ as defined in Business and Professions Code, Section 1206, that is authorized to perform clinical laboratory tests or examinations in California or on a biological specimen originating in California.

This definition identifies the level of laboratory licensure required to perform HIV tests. No person or entity may perform tests to detect the presence of HIV infection unless that person or entity is licensed or certified as a clinical laboratory or public health laboratory. A 'physician office lab' is a type of clinical laboratory that may also be authorized. HIV tests are categorized as moderate or high complexity tests. The

categorization is determined by the CDC and is based on the scientific knowledge and skill required to perform the test. Laboratories that perform moderate or high complexity tests (defined in federal regulation at 42 CFR 493.5) are required to possess a current, unrevoked, state licensed and a Clinical Laboratory Improvement Amendments (CLIA) certificate or a public health microbiologist certificate of approval. Laboratories must report confirmed HIV tests to the local health department as well as the health care provider who submitted the biological specimen for testing.

SECTION 2641.65. LABORATORY TEST.

"Laboratory test" means a clinical laboratory test or examination as defined in Business and Professions Code, Section 1206 (a) (4) and performed by a laboratory as defined in this Article.

Biological specimens are submitted by health care providers to laboratories for testing to determine the presence of HIV, a component of HIV, or antibodies or antigens to HIV. Laboratory test is defined in this Article to explain the use of the term in regulation language and to clarify the agency that may perform these tests.

SECTION 2641.70. LOCAL HEALTH DEPARTMENT.

"Local health department" means the governing body providing public health services to cities and/or counties, as identified in Health and Safety Code, Section 101185.

Local health departments provide oversight and authority for multiple public health programs, including counseling and testing programs. Confirmed HIV test results are reported to the local Health Officer by laboratories and health care providers. Designees of the Health Officer are responsible for matching and unduplicating, and then forwarding unduplicated HIV reports to the Department.

SECTION 2641.75. NON-NAME CODE.

"Non-name code" means a designation required by Section 2645 of this Article that does not readily identify an HIV-infected individual.

The non-name code was created to allow compliance with CDC HIV reporting guidelines, provide epidemiologic information and protect an HIV-infected individual's confidentiality. The non-name code developed for California's HIV reporting system contains many of the elements used by other states for HIV reporting, but is not a replica of any other state's system. Components of the non-name code consist of the HIV-infected individual's Soundex code, the complete birth date (two digit month, two digit day and a four digit year), the patient's gender (male [1], female [2], transgender male to female [3], and transgender female to male [4], and the last four digits of the Social Security Number (if not available, four digits of zero are used.) This code is used in place of the individual's name when a health care provider reports a confirmed HIV test to the local Health Officer.

The Department completed a survey to verify that the proposed components of the non-name code are consistent with the seven other states that report HIV infection in this manner. Comparing California's proposed code with other non-name systems, it was determined that six states use some form of the HIV-infected individual's name and at least a portion of the birth date; four states include gender as part of their code. Six states collect the last four digits of the Social Security Number; five states include it as part of their non-name code and one state uses the four digits only in the event of duplicate HIV case reports. Although none of the seven surveyed states had a coding system identical to California's proposal, five states had at least three elements that were equivalent. California has a substantially larger caseload compared to other states; therefore, the non-name code was designed to minimize the possibility of duplicate HIV reports.

SECTION 2641.80. PERSONAL INFORMATION.

"Personal information" means an individual's complete Social Security Number, complete surname, home address, electronic mail address or telephone number.

This definition clarifies the information that is prohibited from being supplied by laboratories when reporting confirmed HIV test results. To ensure confidentiality of an HIV-infected individual, personal information will not be used in the process of reporting confirmed HIV tests to local or state health departments.

SECTION 2641.85. PUBLICLY-FUNDED CONFIDENTIAL COUNSELING AND TESTING PROGRAM.

"Publicly-funded Confidential Counseling and Testing Program" means a program funded by federal, state or local governmental agencies that provides confidential HIV tests to patients.

These programs, located in counties throughout the state, provide hundreds of HIV tests for their patients each year. For the purpose of this Article, publicly-funded confidential counseling and testing programs are included in the definition of health care provider. These programs will submit an HIV/AIDS Case Report form to the Health Officer for each individual who receives a confirmed HIV test.

SECTION 2641.90. SOUNDEX CODE.

"Soundex code" means a phonetic, alphanumerical formula which is used to convert the first letter and sequential consonants of an individual's surname into a symbol; identified by the Department as form DHS 20001SC (3/01), and hereby incorporated by reference in this Article.

The Soundex Code is one portion of the coding system selected by the Department for use in these proposed regulations and is a necessary element for matching and

unduplicating reported cases. The Soundex Code has been used nationally for nearly 100 years as a method of maintaining the confidentiality of reported cases of communicable disease. It is the standard code used by all states and CDC for AIDS reporting since the beginning of the AIDS epidemic. The Soundex Code is incorporated by reference to reduce general access to the coded information and because it is too cumbersome to include in its entirety within the CCR. The Soundex Code is utilized in accordance with the following thirteen rules:

1. The first letter of the last name is never coded.

2. The vowels A, E, I, O, U, and the letter Y are never coded.

3. The consonants H and W are never coded.

4. Key letters and their equivalents are converted to code numbers.

Key letter	Equivalents	Code Number
B	B, F, P,V	1
C	C, G, J, K, Q, S, X, Z	2
D	D, T	3
L	L	4
M	M, N	5
R	R	6

5. The consonants of the last name, other than the first letter and H and W are converted to their respective code numbers in the order in which they appear in the name. Example: **H**OLMES is converted to H452.

6. The numeric code always consists of three digits. The Soundex code for names which do not contain three key-letters or their equivalents are completed by adding zeros. Zeros follow the assigned number code. Example: **B**AILEY is converted to B400.

7. The Soundex code for names that contain more than three key-letters, or their equivalents, are complete when a three-digit numeric code has been assigned. Example: **V**ONDERLEHR is converted to V536, using only the V, N, D and the first R.

8. Two or more key-letters, or their equivalents, appearing together are treated as one key-letter and are assigned one number. Example: **B**ALLOU is converted to B400, using the B, and only the first L.

9. A key letter, or its equivalent, immediately following an initial letter (first letter of the last name) of the same group or value is not coded. Example: **S**CANLON is converted to S545, using the S, the first N, the L, and the second N.

10. Key-letters, or their equivalents, separated by A, E, I, O, U, or Y are code separately. Example: **H**ANNON is converted to H550, using the H, the first N, and the third N.

11. Key-letters, or their equivalents, separated only by the letter W or the H are coded as one key-letter. Example: **S**CHKOLNIK is converted to S452 using the S, the L, the N, and the second K. The C is not coded because it is in the group equivalent to the letter S and the first K is not coded because it is in the group equivalent to the letter C, from which it is separated only by an H.

12. Abbreviated prefixes such as Mc or St. are coded as if spelled out. Example: ST. JOHN = **S**AINT JOHN which is converted to S532, using the S, the N, the T, and the J.

13. An apostrophe in a name is disregarded. Example: **O**'NEILL is converted to O540.

SUB-ARTICLE 4. REPORTING REQUIREMENTS

SECTION 2643.5. HIV REPORTING BY HEALTH CARE PROVIDERS.

Health and Safety Code, Section 120125 requires the Department to examine the causes of communicable disease occurring or likely to occur in the state, and Health and Safety Code, Section 120130 authorizes the Department to establish a list of reportable communicable or non-communicable diseases. Health and Safety Code, Section 120140 authorizes the Department, upon being informed by a Health Officer of a contagious, infectious or communicable disease, to ascertain the nature of the disease and prevent its spread. This Section identifies the process a health care provider shall follow for submitting a biological specimen to a laboratory and reporting a confirmed HIV test to the local health department.

Submitting a Biological Specimen to the Laboratory

Subsection (a): Each health care provider that orders a laboratory test used to identify HIV, a component of HIV, or antibodies or antigens to HIV shall submit the following to the laboratory performing the test:

- A pre-printed laboratory requisition form which includes all documentation as specified in 42 CFR 493.1105 (57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993) and adopted in Business and Professions Code, Section 1220; **or**

- A completed Confidential Counseling and Testing Site laboratory requisition form DHS 8257A (3/01), hereby incorporated by reference in this Article.

This requirement is consistent with current practices followed by health care providers and helps to avoid inaccurate test result notification and inappropriate medical care. The laboratory requisition form DHS 8257A (3/01) is being incorporated by reference because it is impractical to place it in the CCR.

Subsection (b): The authorized person ordering the test shall provide the laboratory the following information:

- First and third letters of patient's last name **or** DHS client number (as assigned by a publicly-funded confidential counseling and testing program); and
- Patient gender (male; female; transgender male-to-female; or transgender female-to-male); and
- Patient date of birth (month, day, year); and
- Date biological specimen was collected; and
- Name, address, telephone number of the health care provider, the facility where services were rendered; and, if applicable:
- Indication of the patient's choice for "confidential" or "anonymous" testing. (This requirement applies to publicly-funded confidential counseling and testing programs only.)

Laboratory requisition forms submitted with complete information will allow for the timely transfer of important medical information to the health care provider, assist in accurate reporting and help to avoid report duplication.

Reporting a Confirmed HIV Test:

Subsection (c): Each health care provider shall, within seven calendar days of receipt of determination of a patient's confirmed HIV test, report the confirmed test to the local Health Officer for the jurisdiction where the health care provider facility is located.

This requirement is consistent with practices currently followed by health care providers for reporting AIDS cases, and allows for timely reporting. Using the patient's non-name code, the health care provider or staff assigned by the provider shall submit a completed copy of the HIV/AIDS Case Report form to the local Health Officer. Completion of these forms will provide data necessary for performing HIV-related epidemiologic study and will enable the local health department and the Department to unduplicate reports.

Subsection (d): HIV reporting by non-name code to the local Health Officer, via submission of the HIV/AIDS Case Report, shall not supplant the reporting requirements

in Article 1 of this Subchapter when a patient's medical condition progresses from HIV infection to an AIDS diagnosis.

AIDS is an advanced stage of HIV infection. The requirements for reporting an AIDS case include the release of personal information to the local Health Officer. Although a confirmed HIV test is reported to the Health Officer on the same form as an AIDS case, different fields are completed for the two conditions. Additionally, HIV infection is reported by a non-name code and AIDS is reported by name. If the AIDS diagnosis is not reported to the Health Officer, the health care provider would be out of compliance with the reporting mandates of Article 1, Section 2500. Local health department (and ultimately Department) staff use multiple fields within the HIV/AIDS Case Report form to match and unduplicate the reported confirmed HIV tests with AIDS case reports already in the HIV/AIDS case registry database.

Subsection (e): When reporting a confirmed HIV test, a health care provider shall not release a patient's personal information to the local Health Officer except for patients whose clinical conditions meet the AIDS reporting criteria, as specified in Article 1 of this Subchapter.

HIV infection is reported by a non-name code and AIDS is reported by name. If the patient has not received an AIDS diagnosis, reporting of HIV infection by name is against California law.

Subsection (f): A health care provider who receives notification from an out-of-state laboratory of a confirmed HIV test for a California patient shall report the findings to the local Health Officer for the jurisdiction where the health care provider facility is located.

Some health care providers utilize the services of an out-of-state laboratory, and some California patients may test for HIV infection while out-of-state, but request that the results be sent to their California-based health care provider. The provision of this subsection ensures that California health care providers report confirmed HIV test results received from California and out-of-state laboratories in a consistent manner.

Subsection (g): Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the health care provider except as authorized by this Article, or other state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of that individual.

This provision serves to underscore the importance of patient confidentiality during HIV reporting.

Subsection (h): When a health care provider orders multiple HIV-related viral load laboratory tests for a patient, or receives multiple laboratory findings of a confirmed HIV tests the health care provider shall be required to submit only one HIV/AIDS Case Report form, per patient, to the local Health Officer.

Viral load tests are ordered by health care providers for medical conditions other than HIV infection, therefore it is necessary to clarify that the HIV reporting regulations are referring only to HIV-related viral load laboratory tests. Viral load tests are used by the provider to determine the phase of HIV infection. For this reason, multiple tests are taken during the course of the disease process. Additionally, some health care providers or their patients may elect to repeat a test to determine HIV infection. In either of these cases, the regulations require that the health care provider report only one confirmed HIV test per patient. This avoids confusion for the local health department and reduces the amount of time a health care provider spends completing HIV/AIDS Case Report forms.

Components of DHS 8257A (3/01) Laboratory Requisition Form

Health and Safety Code, Section 120125 requires the Department to examine the causes of communicable disease occurring or likely to occur in the state, and Health and Safety Code, Section 120130 authorizes the Department to establish a list of reportable communicable or non-communicable diseases. Health and Safety Code, Section 120140 authorizes the Department, upon being informed by a Health Officer of a contagious, infectious or communicable disease, to ascertain the nature of the disease and prevent its spread. The DHS 8257A (3/01) laboratory requisition form is used by publicly-funded anonymous and confidential counseling and testing sites and other publicly-funded programs to submit a biological specimen to a laboratory for an HIV antibody test. The forms and their accompanying DHS Client Number labels are available from the State Office of AIDS and all local health departments. Fields within the DHS 8257A (3/01) laboratory requisition form are as follows:

- LOCAL LABORATORY NUMBER*:* (This area is reserved for the laboratory number and is used to identify the laboratory where services are provided as well as to track the blood specimen.)

- CLIENT ID NUMBER: (The unique eight-digit DHS Client Number assigned by the anonymous or confidential counseling and testing site. The number is used to ensure client anonymity, track the blood specimen, and assist in record keeping. In the event of a confirmed HIV test, the number will assist the local health department in matching/unduplicating case reports.)

- DATE OF SPECIMEN: (The specimen date identifies when the blood specimen was taken and is used to track the volume and timeliness of testing at each laboratory site. In the event of a confirmed HIV test, this information will assist in matching and unduplicating reported tests.)

- POST TEST SESSION, *Yes/No*: (Indicates that the test results were disclosed to the client and that counseling and referral services were conducted. This field assists counseling and testing sites in determining whether or not clients have returned for their test results.)

- CLIENT TEST ELECTION, *Anonymous/Confidential:* (This field indicates if the patient has chosen to test anonymously or confidentially. Indicating the type of testing assists laboratories and the counseling and testing programs in determining which confirmed HIV test results are to be reported to the local health department. Confirmed HIV tests for patients who test anonymously are not included in California's HIV reporting system.)

- GENDER: (Indicates the client's gender as male, female, transgender male-to-female or transgender female-to-male. In the event of a confirmed HIV test, this information will assist in matching/unduplicating reports. Gender is used in surveillance, data analysis, and targeting prevention programs and assists in matching patients to their results during the post test session with the patient.)

- DATE OF BIRTH*: (*Two-digit month, two-digit day and four-digit year. In the event of a confirmed HIV test, this information will assist in matching/unduplicating reported HIV cases. Date of birth is used in surveillance, data analysis, and targeting prevention programs. It also assists in matching patients to their results during the post test session.)

- COUNTY OF RESIDENCE: (Indicates the county where the client has his/her primary residence, and is used in demographic analysis of the epidemic. Residence county identifies the geographic location of the patient and is used in surveillance and data analysis and for targeting prevention programs. It also assists in matching clients to their results during the post test session.)

- ZIP CODE: (Indicates the zip code of the client's residence and is used in demographic analysis of the epidemic. Residence zip code determines the geographic location of the patient and is used in surveillance and data analysis and also assists in matching patients to their results during the post test session.)

- PREVIOUS HIV ANTIBODY TEST, *Yes/No/Unknown/When/ID#:* (These fields provide information on the number of clients that seek repeat HIV testing. The number of previous HIV antibody tests provides a history of past laboratory services and identifies clients who repeatedly test. This information is used in HIV surveillance, data analysis and assists in directing prevention programs.)

- RESULT OF PREVIOUS TEST*, Positive/Negative/Unknown:* (These fields provide information on the number of HIV positive/negative clients who repeat testing. The results from a previous HIV test provide additional information on the patient testing history and help to identify patterns of testing behaviors in data analysis.)

- LABORATORY NAME, ADDRESS: (Lists the name and address of the laboratory that will receive the specimen and perform the test. This information provides contact information should it be necessary.)

- CLINIC/SITE*:* (Indicates the name, address, and telephone number of the clinic or site where the specimen was obtained. This field allows laboratories to identify where test results are to be sent. In the event of a confirmed HIV test result, this information will assist in matching/unduplicating reported cases.)

- RETURN APPOINTMENT DATE*:* (Used by clinic/site staff to indicate the month, day and year the client should return for the test results. The return appointment date also indicates to the laboratory when the test results should be delivered to the testing sites to ensure that results are delivered prior to the patient's appointment.)

- LABORATORY USE ONLY

  ELISA, Reactive/Non-Reactive: (The enzyme-linked immunosorbent assay, ELISA, is a test used to check for the presence of antibodies to HIV in blood samples. Reactive results of ELISA indicate the presence of HIV antibodies in the blood and require a supplemental test to confirm results. Non-reactive results indicate that no HIV antibodies were found. The results of the ELISA test are used in the post test session to explain test results to patient and for HIV surveillance and data analysis.)

  SUPPLEMENTAL TEST PERFORMED

  IFA, Reactive/Non-Reactive/Nonspecific/Unsatisfactory: (The immunofluorescent assay (IFA) is a type of test used to check for the presence of antibodies to HIV in blood samples. It is usually used after a positive result is reported on an ELISA. Reactive indicates that HIV antibodies were found; non-reactive indicates that no antibodies were found; nonspecific/unsatisfactory indicates that the results could not be interpreted as reactive or non-reactive. IFA test results are used in the post test session to explain test results to patients and for HIV surveillance and data analysis.)

  Western Blot, Reactive/Non-reactive/Indeterminate: (A type of test used to check for the presence of antibodies to HIV in blood samples. It is usually used as a confirmatory test after a positive result is reported on an ELISA. Reactive indicates the presence of HIV antibodies; non-reactive indicates the results were negative; indeterminate indicates that the results were inconclusive. The results of the Western Blot test are used in the post test session to explain test results and for HIV surveillance and data analysis.)

  SUMMARY INTERPRETATION:

  HIV Antibody Detected: (Box is marked if test was positive. This box provides an additional confirmation of tests by providing a summary of test results and assists the disclosure counselor during the post test session when explaining results to patients.)

No HIV Antibody Detected: (Box is marked if test was negative. This box provides an additional confirmation of tests by providing a summary of test results and assists the disclosure counselor during the post test session when explaining results to patients.)

Inconclusive-Submit Another Specimen: (Box is marked if the test was indeterminate and another specimen is needed for testing. This field assists the disclosure counselor during the post test session when explaining results to patients.)

See Enclosed Note: (Laboratory notes to the clinic/site regarding test. This field informs the post test disclosure counselor that additional notes on the results of the test are included with the form.)

DATE RECEIVED BY LAB: (Used by the laboratory to record when the specimen was received. The date the specimen was received by the laboratory assists in the scheduling of laboratory procedures. This date also evaluates the timeliness of the submission of the specimen to the laboratory by the health care provider.)

DATE REPORTED: (Indicates the date the laboratory reported the results to the submitting provider of service and confirms that results have been sent to the testing site for the post test session with the patient. This date will also be used during the post-implementation evaluation of HIV reporting to determine if CDC guidelines for the timeliness of reporting are being met.)

- ATTACH LABEL TO REPORT FORM AND BLOOD SPECIMEN: (A series of labels all with the same unique DHS Client Number are attached to each laboratory requisition form. One label is placed on the client record, one on the laboratory requisition form and one on the biological specimen container. Remaining labels are sent to the laboratory performing the test to assist with record keeping in the laboratory. The use of the DHS Client Number maintains the confidentiality of the patient and assists the counseling and testing program, the laboratory and ultimately the local health department in tracking and unduplicating.)

Components of the California DHS HIV/AIDS Confidential Case Report Form

Health and Safety Code, Section 120125 requires the Department to examine the causes of communicable disease occurring or likely to occur in the state, and Health and Safety Code, Section 120130 authorizes the Department to establish a list of reportable communicable or non-communicable diseases. Health and Safety Code, Section 120140 authorizes the Department, upon being informed by a Health Officer of a contagious, infectious or communicable disease, to ascertain the nature of the disease and prevent its spread.

The California DHS Adult or Pediatric (2001A and 2001B, revised 3/01) HIV/AIDS Confidential Case Report forms provide data for public health surveillance, and assist in

the development of education, prevention, early intervention, care and treatment programs that serve HIV-infected individuals. The forms are available from the State Office of AIDS and all local health departments. Form DHS 2001A is to be used for all HIV/AIDS case reports of HIV-infected patients age 13 years and older at the time of diagnosis, and form DHS 2001B is to be used for patients under 13 years.

Both forms will be used for reporting HIV infection as well as an AIDS diagnosis, thus providing continuity in monitoring HIV disease. Some fields within the forms are only used when reporting an AIDS diagnosis. The California DHS Adult or Pediatric (2001A and 2001B, revised 3/01) HIV/AIDS Confidential Case Report forms are incorporated by reference in the proposed new Article 3.5. For the sake of brevity, the forms are defined as the HIV/AIDS Case Report forms. These forms are being incorporated by reference because they are too cumbersome to place in the CCR in their entirety. Fields within the forms are as follows:

- *Date Form Completed:* (This information is necessary to establish and compare when the form was completed to when the HIV infection was first determined.)

- *Diagnosis Status at Report:* (Indicates if the patient is HIV-infected or if the infection has progressed to AIDS. This information helps to identify which parts of the form should be completed and is scanned during electronic monitoring of the report to collect specific data elements.)

- HEALTH DEPARTMENT USE ONLY

  *Reporting HD: (*Identifies the city/county jurisdiction of origin that is reporting the HIV case information. The information allows the state to follow up on erroneous or incomplete information entered on individual case reports and helps to examine the workload associated with case finding and monitoring by the local health department.)

  State Patient No.: (The HIV/AIDS Reporting System [HARS] number assigned to an HIV case report by the local or state health department to assist in file management. CDC also uses this number to generate reports or to inquire about a case.)

- FOR HIV & AIDS CASES – ESSENTIAL INFORMATION

  Soundex Code: (A phonetic, alphanumeric four-digit code comprised of the first letter of the patient's last name and numbers representing sequential consonants. The Soundex code is one of the matching variables used to track individual HIV/AIDS cases without revealing the identity of the individual. It is the standard used by all states and CDC since the beginning of the AIDS epidemic. The Soundex code is created by the health care provider and is part of the non-name code used for HIV reporting. Health care providers do not complete this portion of the HIV/AIDS Case Report for an AIDS patient, since AIDS is reported by name.)

Date of Birth: (Two-digit month, two-digit day and four-digit year; the patient date of birth is part of the non-name code used for HIV reporting.)

Gender: (Patient will be identified as either male [1], female [2], transgender male-to-female [3], or transgender female-to-male [4]. Gender identification is part of the non-name code used for HIV reporting and is also used in epidemiologic analysis of the epidemic.)

Last four digits of the Social Security Number: (These numbers are part of the non-name code used for HIV reporting and will assist in matching and unduplicating case reports. Use of the last four digits of the Social Security Number is consistent with most states that require HIV surveillance by a unique identifier. Health care providers will not be required to complete this section of the form when reporting an AIDS case. [See "For AIDS Cases Only," below.]

Lab test number: (Laboratory-generated report number, specific to the HIV test, which will be used by the local health department when matching reported HIV cases. This number is not part of the patient's non-name code.)

Confidential C&T Number: (This unique eight-digit DHS Client Number is assigned by a publicly-funded confidential counseling and testing program. The counseling and testing program uses this number when submitting a biological specimen to the laboratory. The local health department uses the number to recognize that a counseling and testing program generated the report and to match the report with confirmed HIV test reports from laboratories. This number is not completed for an AIDS patient, and it is not part of patient's non-name code.)

- DEMOGRAPHIC INFORMATION

Current Status: (The status of cases classified as alive, dead, or unknown is essential in determining the number of people living with HIV/AIDS.)

Date of Death: (Establishes closure on the case history.)

State/Territory of Death: (Specifies the geographic area where the patient died and assists with the analysis of migration patterns.)

Race/Ethnicity: (Cultural differences often dictate behaviors. This information allows the opportunity to more accurately target efforts for education and prevention services.)

Country of Birth: (Identifies the country where the HIV-infected individual was born and is used in monitoring geographic patterns of infection.)

Residence at Diagnosis: (Determines which health jurisdiction may claim the case [which helps determine funding allocations] and assists with the analysis of migration

patterns. If a patient is diagnosed with HIV infection in one county, progresses to AIDS and is then diagnosed as an AIDS case in another county, the residence at diagnosis will remain with the health jurisdiction in which the patient lived when the first confirmed HIV test was reported.)

- FACILITY OF DIAGNOSIS

  This block of fields identifies the name, location, and type of facility where the HIV-infected person was tested and determines if the facility is public, private, or federal. This information is important for follow up purposes, helps to determine where to focus outreach for HIV testing and identifies patterns of testing.

- PATIENT HISTORY (2001A) or PATIENT/MATERNAL HISTORY (2001B)

  This block of fields identifies how the HIV infection may have been transmitted from one person to another, and is necessary for the targeting of specific risk behaviors for education and prevention efforts. The pediatric form contains information about the HIV status of the child's biological mother, since most pediatric cases of HIV infection are the result of maternal transmission.

- LABORATORY DATA

  HIV Antibody Tests at Diagnosis: (Identifies the antibody test used to determine that the person was infected with HIV and establishes the date the test occurred. In the event of multiple reports for the same individual, the test date is used by the local health department to determine first confirmation of HIV infection. Information regarding the type of test is used to reveal trends in testing methods.)

  Positive HIV Detection Test: (Identifies a method other than an antibody test, such as a viral load test, to determine that an individual is HIV-infected. It establishes the date the test occurred and is used to observe trends in testing methods.)

  Immunologic Lab Tests: (Determines the level of CD4 + cells in the body which indicates the stage of HIV infection and establishes the date of the test. This is section is currently used only for AIDS reporting.)

- FOR AIDS CASES ONLY

  Patient Name, Medical Record Number, Social Security Number, Address, City, County, State, Zip Code: (With the exception of the Social Security Number, these fields are currently found on the CDC HIV/AIDS Confidential Case Report form. In California, when reporting an AIDS case, the Social Security Number is usually entered in the COMMENTS section of the form. For consistency, the revised HIV/AIDS Case Report form, to be used upon implementation of California's HIV reporting system, will contain a specific field for the SSN. All fields are used by the local health department and the Department for unduplicating and for

epidemiological study. The information is not transmitted to CDC.)

- AIDS-DEFINING CONDITIONS

  Clinical Record Reviewed: (Identifies whether a patient's clinical record was reviewed for the purpose of completing the case report and/or confirming the validity of the test result. This information is necessary to verify that available medical information has been reviewed to confirm that the patient has been diagnosed with AIDS.)

  AIDS Indicator Diseases: (Indicates either a presumptive or definitive diagnosis that HIV infection has progressed to AIDS, and notes the date of the diagnosis. An AIDS diagnosis consists of HIV infection in conjunction with one or more identified clinical conditions. This field lists the identified clinical conditions in such a manner that the health care provider can check the boxes of those conditions that apply to the patient. This field is not used to report HIV infection without an AIDS diagnosis.)

- BIRTH HISTORY

  For perinatal cases only: (These fields are only found on the pediatric form and are used when, at birth, an infant shows evidence of antibodies to HIV. Most children in California become HIV-infected through perinatal transmission. Epidemiologic data gathered from these fields provide important information regarding the mother's prenatal care (including the use of anti-retroviral medications during pregnancy), the type of delivery, the birth weight and whether the infant was full term or premature. This information is used in HIV surveillance, data analysis and assists in targeting HIV prevention programs.)

- TREATMENT/SERVICES REFERRALS

  This child received or is receiving: (Indicates if the child has been given any type of anti-retroviral medication to help prevent or treat HIV infection. This information is necessary to examine the effectiveness of HIV medications in pediatric cases. This question is only found on the pediatric HIV/AIDS Case Report form).

  Was child breastfed? Yes/No/Unk: (Indicates if a child was breastfed as an infant. If a child shows no evidence of antibodies to HIV at birth, but develops the antibodies at a later date, and the child has been breastfed, this indicates the possibility of maternal transmission of HIV through breast milk. Data regarding breastfed children and HIV provides an important base for epidemiologic research on post-delivery maternal transmission of HIV. This question is only found on the pediatric HIV/AIDS Case Report form.)

  Has this patient been informed of his/her HIV infection: (Indicates if a patient has been informed of his/her HIV status. Early patient notification of HIV status is crucial for the protection of the patient's health as well as the health of others. Examples of

patients that may not be informed of their HIV infection include but are not limited to minor children and patients that do not return for laboratory test results.)

This patient's partners have been or will be notified about their HIV exposure and counseled by: (Partner notification is a voluntary process in California, but many health care providers recommend some type of partner notification to the patient when informing the patient of his/her HIV status. This field identifies the patient's preference (if any) for who will be responsible for providing partner referral services to the patient's partners. Choices include the health department, provider, the patient or an unknown person. Knowledge of a partner's HIV status provides the opportunity to make decisions that will help to prevent the spread of HIV.)

This patient is receiving or has been referred for: (Identifies if the patient is receiving HIV-related medical services, or substance abuse treatment services. This information helps determine if the patient is in the health care network and provides for the opportunity for the counseling and testing program or the local health department to offer early intervention and referral services for the patient.)

This patient received or is receiving: (Identifies if the patient has received or is receiving anti-retroviral therapy and/or post-exposure prophylaxis. This information helps determine if the patient is in the health care network and provides an opportunity for the counseling and testing program or the local health department to refer the patient for early intervention services.)

This patient's medical treatment is primarily reimbursed by: (Identifies the source of funding used to pay for a patient's medical treatment, and is useful for the analysis of current and future governmental and private agency funding.)

For Women: (Identifies if the patient is receiving or has been referred for gynecological or obstetrical services and if the patient is pregnant or has delivered live-born infants. It also provides information about the child's date and location of birth. Certain opportunistic infections and/or cancers are associated specifically with women. Women with HIV infection are capable of transmitting the infection to their fetus during pregnancy and/or delivery and their infant during breastfeeding. This information provides for the opportunity of appropriate follow-up and to determine potential care and services issues for children of HIV-infected mothers.)

- PROVIDER REPORTING INFORMATION

(These fields include provider name, telephone number, hospital/facility name and the name of the person completing the form along with their telephone number. This information is used by the local health department and the Department in numerous ways including: contact information in the event of incomplete patient information; case matching; and monitoring of the case workload of the local health department. The information will not be forwarded to the CDC.)

SECTION 2643.10. HIV REPORTING BY LABORATORIES.

Health and Safety Code, Section 120125 requires the Department to examine the causes of communicable disease occurring or likely to occur in the state, and Health and Safety Code, Section 120130 authorizes the Department to establish a list of reportable communicable or non-communicable diseases. Health and Safety Code, Section 120140 authorizes the Department, upon being informed by a Health Officer of a contagious, infectious or communicable disease, to ascertain the nature of the disease and prevent its spread. This Section explains the requirements for laboratories to report confirmed HIV tests to the local Health Officer.

Subsection (a): The laboratory director, or his or her authorized designee shall, within seven calendar days of determining a confirmed HIV test, report the confirmed HIV test to the local Health Officer for the jurisdiction where the health care provider facility is located. The report shall include the:

- First and third letters of the patient's last name **or** the DHS client number; and
- Patient gender (male, female, transgender male-to-female or female-to-male); and
- Patient date of birth; and
- Name, address, and telephone number of the health care provider and facility that submitted the biological specimen to the laboratory; and
- Name, address, and telephone number of the laboratory; and
- Laboratory report number as assigned by the laboratory; and
- Laboratory results of the test performed; and
- Date the biological specimen was tested in the laboratory.

Laboratories currently are required by regulation (Title 17, CCR, Section 2505) to report certain communicable diseases to the local Health Officer. The HIV reporting requirement extends that responsibility to include confirmed HIV test results. Laboratory reports of confirmed HIV tests to local Health Officers will assist in determining the number and geographic location of persons infected with HIV and will serve as a control for monitoring HIV/AIDS Case Reports submitted by health care providers. The information reported by the laboratory to the Health Officer will assist in matching and unduplicating confirmed HIV test results and will allow the Health Officer to contact the health care provider or the laboratory, should it be necessary.

Subsection (b): A laboratory shall not transmit a patient's personal information to the local health department.

Some health care providers send personal information to the laboratory on a laboratory requisition form. This provision serves to underscore the importance of patient confidentiality during HIV reporting.

Subsection (c): A laboratory that receives incomplete patient data from a health care provider for a biological specimen with a confirmed HIV test, shall contact the submitting health care provider to obtain the patient information required pursuant to (a) of this Section prior to reporting the confirmed HIV test to the local Health Officer.

This requirement ensures that information reported by the laboratory to the Health Officer is sufficient to allow for the initial matching and unduplicating of other confirmed HIV reports.

Subsection (d): A laboratory shall include the test requisition form when transferring a biological specimen to another laboratory for testing. The laboratory that first receives the biological specimen from the health care provider shall report confirmed HIV tests to the local Health Officer.

This requirement is consistent with current laboratory practices for reporting other communicable diseases.

Subsection (e): Laboratories shall not be required to submit reports to the local health department for confirmed HIV tests for patients of an Alternative Testing Site or other anonymous HIV testing program, a blood bank, or for participants of a blinded and/or unlinked seroprevalence study.

Justification for these exemptions is explained in the Initial Statement of Reasons, Section 2643.20 (HIV Reporting Exemptions), below.

Subsection (f): When a California laboratory receives a biological specimen for testing from an out-of-state laboratory or health care provider, the California director of the laboratory shall ensure that a confirmed HIV test is reported to the state health department in the state where the biological specimen originated.

Some health care providers utilize the services of a laboratory in another state, especially if that laboratory is geographically closer. Additionally, an out-of-state laboratory may send a biological specimen to a California laboratory for testing. HIV reporting is mandated in the majority of states; this subsection ensures that California laboratories report confirmed HIV tests to the appropriate state health department. The state health department where the biological specimen originated will use the laboratory report for matching and unduplicating if HIV infection is a reportable condition in that state. If HIV is not reportable in that state, the state health department will destroy the laboratory report.

Subsection (g): Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the laboratory except as authorized by this Article, other

state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of the individual.

This subsection is necessary to underscore the importance of maintaining patient confidentiality when reporting HIV.

SECTION 2643.15. HIV REPORTING BY LOCAL HEALTH OFFICERS.

Health and Safety Code, Section 120125 requires the Department to examine the causes of communicable disease occurring or likely to occur in the state, and Health and Safety Code, Section 120130 authorizes the Department to establish a list of reportable communicable or non-communicable diseases. Health and Safety Code, Section 120140 authorizes the Department, upon being informed by a Health Officer of a contagious, infectious or communicable disease, to ascertain the nature of the disease and prevent its spread. This subsection describes the requirements for HIV reporting by Health Officers of local health departments.

Subsection (a): The local Health Officer or his or her authorized designee shall match and unduplicate laboratory reports of confirmed HIV tests with the local health department HIV/AIDS registry database and with HIV/AIDS Case Reports received from health care providers and not entered into the database.

This will help to ensure the completeness of HIV reporting and avoid duplication. For laboratory reports without a match, surveillance staff assigned by the local Health Officer shall contact the health care provider to offer assistance in completing the HIV case report.

The Department performed a preliminary assessment to determine if the proposed laboratory reporting elements are sufficient for local health departments to match and unduplicate laboratory reports with the existing HIV/AIDS registry and with new HIV/AIDS Case Reports. Over 26,000 AIDS cases reported from a large California local health department formed the cohort of the assessment. Two options for laboratory reporting elements were considered: 1) first letter of the patient's last name, date of birth, gender; 2) first and third letters of the last name, date of birth, gender. Results showed that matching and unduplication of cases with the registry database was possible for 94.5% of the cases using the components of Option One. The addition of the third letter of the last name in Option Two resulted in a matching/unduplication rate of 99.4%. To achieve a highly reliable match of laboratory reports with HIV/AIDS registry data at the local health department and to meet CDC minimum standards for unduplication, Option Two was selected. For laboratory reports not matched with the registry database, local health department surveillance staff shall use the additional laboratory reporting elements, noted in Section 2643.10 (a), as an adjunct for matching HIV case reports from health care providers.

Subsection (b): The Health Officer or his or her authorized designee shall, within 45 calendar days of receipt of a laboratory report of a confirmed HIV test, submit

unduplicated HIV/AIDS Case Reports to the Department. HIV/AIDS Case Reports shall be sent by courier or mail to California Department of Health Services, Office of AIDS, HIV/AIDS Case Registry. The Health Officer or designee shall not submit reports for patients of an Alternative Testing Site or other anonymous counseling and testing program, a blood bank, or for participants of a blinded and/or unlinked HIV seroprevalence study.

Requirements for HIV reporting by the local Health Officer to the Department are consistent with current procedures used when a Health Officer reports an AIDS case. The justification for HIV reporting exemptions is explained in the Initial Statement of Reasons, Section 2643.20 (HIV Reporting Exemptions), below.

Subsection (c): The local Health Officer or his or her authorized designee shall retain in the local health department HIV/AIDS registry a HIV/AIDS Case Report for an infant under the age of 18 months until the infant's HIV infection is confirmed.

Infants of HIV-infected mothers potentially may contract HIV by perinatal exposure or may show evidence of HIV antibodies in their blood for more than a year after birth, but not truly be HIV-infected. To prevent erroneous reports, case reports for HIV-positive infants under the age of 18 months will be required to be held in the local health department HIV/AIDS database until HIV infection is confirmed. Upon confirmation, the case report shall be forwarded to the State Office of AIDS.

Subsection (d): Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the local Health Officer or his or her authorized designee except as authorized by this Article, other state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of the individual.

This provision serves to underscore the importance of patient confidentiality during HIV reporting.

SECTION 2643.20. HIV REPORTING EXEMPTIONS.

Alternative Testing Sites, other anonymous or unlinked HIV testing programs, blood banks and blinded and/or unlinked seroprevalence studies are exempt from this HIV reporting regulation.

HIV reporting exemptions have been made for the following reasons:

- Health and Safety Code Section 120895 governs the provisions for anonymity of testing at an Alternative Testing Site. These sites do not collect any type of information that links a person's identity to the test result. Although not statutorily mandated, other types of anonymous testing programs also exist throughout the state and also do not collect any type of patient information. The lack of patient

information creates an inability for Alternative Testing Sites or other anonymous testing programs to follow the mandates of Section 2643.5.

- Health and Safety Code, Section 1603.1 requires that all blood and blood components to be used in humans are tested for HIV. Blood bands and plasma centers must report the name and other personal information of HIV-infected donors to the Department of Health Services. The purpose of HIV reporting by non-name code is to protect the identity of the HIV-infected individual. Since HIV-infected blood donors are already reported by name, it is pointless for blood banks or plasma centers to report HIV by non-name code.

- Blinded or unlinked seroprevalence studies do not collect information from study participants, which creates the inability to follow the mandates of Section 2643.5.

SUB-ARTICLE 6. NON-NAME CODE

SECTION 2645. COMPONENTS OF THE NON-NAME CODE.

Health and Safety Code, Section 120125 requires the Department to examine the causes of communicable disease occurring or likely to occur in the state, and Health and Safety Code, Section 120130 authorizes the Department to establish a list of reportable communicable or non-communicable diseases. Health and Safety Code, Section 120140 authorizes the Department, upon being informed by a Health Officer of a contagious, infectious or communicable disease, to ascertain the nature of the disease and prevent its spread. This subsection identifies the components of the non-name code to be used in California's HIV reporting system.

The health care provider shall create a non-name code for each patient with a confirmed HIV test that has not received an AIDS diagnosis. Components of the non-name code shall consist of an individual's:

Subsection (a): Soundex code

The Soundex code is the standard used by all states and CDC since the beginning of the AIDS epidemic. The Department obtained the code from CDC, and it has been applied nationally for nearly 100 years as a method of maintaining the confidentiality of reported cases of communicable disease.

Subsection (b): Patient's birth date

The birth date shall be reported as a 2-digit month, 2-digit day, and a 4-digit year. For example, coding for an individual born on January 1, 1965 would be reported as 01011965. This information will be used to conduct epidemiological studies.

Subsection (c): Patient's gender

Gender shall be reported as male [1], female [2], transgender male to female [3], or transgender female to male [4]. This information will be used to conduct epidemiological studies.

Subsection (d): Last four digits of patient's Social Security Number.

If the patient does not have a Social Security Number, or if it is unavailable, four digits of zero (0000) shall be used to complete the non-name code.

When used together, the four elements of the non-name code establish a unique symbol that does not readily identify the HIV-infected individual. Use of these elements is consistent with other states that report HIV infection by unique identifier. The Department has made the initial determination that the proposed elements of the non-name code are crucial components for correctly matching and unduplicating HIV case reports and meeting the CDC minimum performance standards.

DOCUMENT RELIED UPON

The following document was relied upon for formulating the reasoning behind the development of the HIV reporting regulation:

CDC. Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome. MMWR 1999; 48 (No. RR-13).

STATEMENTS OF DETERMINATION

A. ALTERNATIVES CONSIDERED

The Department has determined that no reasonable alternative considered by the Department, or that has otherwise been identified and brought to the attention of the Department, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

The Department considered the following alternatives to HIV reporting by non-name code:

Reporting by name:
California law prohibits releasing the name of an individual infected with HIV except under specific circumstances. In the absence of a change in California statute(s), HIV reporting by name is against the law.

Results of a 1998 study, released by the CDC, determined that individuals at high-risk for HIV infection cited "concern about having one's name reported to the government" as a factor for not seeking HIV testing.

HIV reporting by name has been legislatively proposed in California and has uniformly received broad opposition from AIDS community advocates, AIDS service providers and people living with HIV/AIDS. These opponents cite studies that suggest HIV reporting by name discourages high-risk individuals from seeking HIV counseling and testing services for fear of discrimination, including the inability to obtain health insurance and employment.

Reporting by a hybrid of name and code:
The hybrid system of reporting considered by the Department entailed the release of an HIV-infected individual's name to the local health department as part of the HIV case report. The local health department would convert the name to a code within a given period of time, and then destroy evidence of the individual's name. The anticipated benefit of this method simplifies the reporting process for health care providers and enables local health departments to easily unduplicate HIV case reports. However, because names are reported to the local health department, in the absence of a change in California statute, this method of HIV reporting is against the law.

Reporting without the use of any identifier:
This option was rejected for a number of reasons. A system that reports HIV infection without any accompanying demographic information defeats the purpose of public health surveillance, for no useful population-specific data is obtained. Reporting without identifier creates the probability of duplicate case reports for the same individual, and could potentially lead to the submission of

inflated numbers of case reports. Additionally, it is not possible to use this option and remain in compliance with the CDC guidelines for HIV reporting.

No reporting:
California has the second largest number of reported AIDS cases in the nation, yet the incidence of HIV infection, the precursor to AIDS, is unknown. California is one of a very few states that do not report cases of HIV infection. To report AIDS and not report the incidence of HIV infection denies the opportunity to: 1) monitor the occurrence of a serious communicable disease; 2) appropriately plan, implement and evaluate public health interventions and programs; 3) preserve and improve public health; 4) enhance local, state and federal efforts to prevent HIV transmission; and 5) more appropriately target funding for HIV education and prevention, early intervention and treatment and care services.

Recent congressional amendments to the federal Ryan White Comprehensive AIDS Resources Emergency (CARE) Act require the Administration to, beginning in 2005, base CARE Act funding on the number of estimated living HIV and AIDS cases, rather than estimated living AIDS cases alone. On, or before, July 1, 2004, the Secretary of Health and Human Services shall determine whether HIV case data, as reported and confirmed by the Director of CDC, is sufficiently accurate and reliable from all eligible areas and states for use in the formula. If the Secretary makes an adverse determination regarding HIV case data, only AIDS case data will be used in fiscal year (FY) 2005 formula allocations. Upon adverse determination, technical assistance to states and eligible areas will be provided to ensure that accurate and reliable HIV case data is available no later than FY 2007. Without an accurate and efficient system to report HIV infection, California will not be competitive with other states, and the State's CARE Act funding will be drastically reduced.

B. LOCAL MANDATE DETERMINATIONS

These regulations would mandate that local health departments report cases of HIV infection to the State health department and would create a mandate for local health departments that is reimbursable according to Section 6 of Article XIII B of the California Constitution and Sections 17500 et seq. of the Government Code.

Funds in the amount of $1,431,000 have been approved and made available in the FY 2000-2001 State baseline budget to help local health departments accomplish this mandate.

The cost impact of HIV reporting on each local health department can only be determined by the number of HIV cases reported in each jurisdiction; the level of completeness of the HIV/AIDS case report forms submitted by health care providers; the level of assistance required by health care providers to complete

the forms; and the time required by health department technical staff to unduplicate HIV reports.

Upon receipt of an HIV/AIDS Case Report form from health care providers, it is estimated that local health department surveillance staff would require approximately five minutes to verify completion of the information for each report, and forward unduplicated reports to the State Office of AIDS. This estimate assumes that all data fields on the reporting form are complete.

C. ECONOMIC IMPACT STATEMENT

The Department has made an initial determination that the adoption of these regulations would not have significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The proposed regulations would not significantly affect the creation or elimination of jobs within the State of California.

The proposed regulations would not cause the creation of new businesses or the elimination of existing businesses within the State of California.

The proposed regulations would not cause the expansion of businesses currently doing business within the State of California.

Description of Direct Cost Impacts on Representative Private Persons or Businesses to Reasonably Comply with the Proposed Regulations:

The process of reporting HIV infection by laboratories and health care providers is similar to established reporting mechanisms for other communicable diseases, none of which have been shown to cause a significant statewide adverse economic impact.

An education and training component for parties impacted by HIV reporting requirements has been included in the State Office of AIDS budget as part of the HIV reporting implementation process. As a result, it is anticipated that laboratories, health care providers and local health departments will incur minimal training costs.

1. Laboratories:
This proposal affects laboratories that are authorized under federal and state law to perform moderate or high complexity laboratory tests. It is estimated that laboratory personnel would require no more than five minutes to report the laboratory results to the health care provider and the local Health Officer. The actual cost impact on the laboratory can only be determined by the number of

confirmed HIV tests, and the salary level of the staff reporting the results to health care providers and local health departments.

Laboratories will follow usual and customary communicable disease reporting methods and will submit either electronic or hard copy reports. For laboratories that report electronically, implementation of HIV reporting may require the addition of a set of fields in the laboratory's computer. Otherwise, no specialized forms or equipment will be required for the laboratory reporting of HIV infection. Information required for HIV reporting by a laboratory is consistent with patient data supplied by providers on standard laboratory test requisition slips. For this reason, it is anticipated that there will be minimal need for a laboratory to contact health care providers to complete patient information.

2. Health Care Providers:
As stated on page 2 of 2 of the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention HIV/AIDS Confidential Report Form, the burden of the collection of information (required for HIV reporting) is estimated to average 10 minutes per response. This time includes reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The California DHS Adult (2001A, revised 1/01) or Pediatric (2001B, revised 1/01) HIV/AIDS Confidential Case Report forms are modifications of the CDC forms and will require a similar period of time to complete.

An accurate estimate of the cost impact of HIV reporting on health care providers can only be determined by the actual number of patients with a confirmed HIV test and the manner in which the provider reports HIV cases. Some health care providers currently have staff assigned to complete the HIV/AIDS case report form. Other health care providers may need to train staff to complete the reporting form, or may require the assistance of local health department surveillance staff.

3. Private Persons:
This Department is not aware of any cost impacts that a representative private person would incur in reasonable compliance with the proposed action.

D. EFFECT ON SMALL BUSINESSES

The Department has made the initial determination that adoption of these regulations will affect small businesses required to comply.

Currently, laboratories report all test results to the submitting health care provider and, by law, both laboratories and health care providers report specified communicable and non-communicable diseases to the local Health Officer. These regulations will add confirmed HIV test results to the list of conditions

reportable to the local Health Officer by both laboratories and health care providers.

E. EFFECT ON HOUSING COSTS

The Department has made the initial determination that the adoption of these regulations would not have a significant statewide effect on housing costs.

F. REPORTING REQUIREMENTS IMPOSED ON BUSINESSES

The Department finds that reports required of health care providers and laboratories by this proposal are necessary for the protection of the health, safety and welfare of Californians.

PROPOSED REGULATIONS

Article 3.5 Reporting of Human Immunodeficiency Virus (HIV) Infection

Sub-Article 1. Definitions

(1) Adopt Section 2641.5 as follows:

Section 2641.5 Alternative Testing Site.

"Alternative Testing Site" means an anonymous HIV testing site funded by the California Department of Health Services, administered by a county health department and operated pursuant to Health and Safety Code, Sections 120890-120895.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(2) Adopt Section 2641.10 as follows:

Section 2641.10. Anonymous Counseling and Testing Program.

"Anonymous Counseling and Testing Program" means a program offering HIV counseling and testing while maintaining anonymity of the patient.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(3) Adopt Section 2641.15. as follows:

Section 2641.15. Anonymous HIV Test.

"Anonymous HIV Test" means an HIV test that maintains the anonymity of the patient.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(4) Adopt Section 2641.20 as follows:

Section 2641.20. Biological Specimen.

"Biological specimen" means any material that is derived from the human body.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Section 1206, Business and Professions Code; Sections 100180, 101160, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(5) Adopt Section 2641.25 as follows:

Section 2641.25. Confidential HIV Test.

"Confidential HIV Test" means an HIV test that links the test results to the patient in a restricted manner to protect against unauthorized disclosure of the identity of the patient.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(6) Adopt Section 2641.30 as follows:

Section 2641.30. Confirmed HIV Test.

"Confirmed HIV test" means the presence of HIV infection as determined by any clinical laboratory test or examination used to detect the presence of HIV, a component of HIV, or antibodies or antigens to HIV, including the HIV antibody (HIV-Ab), HIV p-24 antigen, Western blot (Wb), Immunofluorescent assay (IFA), viral load and virus isolation test.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1241, 1265 and 1281, Business and Professions Code; Sections 100180, 101150, 101160, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(7) Adopt Section 2641.35 as follows:

Section 2641.35. Department.

"Department" means the California Department of Health Services, Office of AIDS.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(8) Adopt Section 2641.40 as follows:

Section 2641.40. DHS Client Number.

"DHS Client Number" means a unique eight digit number created by the California Department of Health Services and assigned to the patient by a publicly-funded confidential counseling and testing program.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(9) Adopt Section 2641.45 as follows:

Section 2641.45. Health Care Provider.

"Health care provider" means an individual authorized by his or her scope of practice as specified in the Business and Professions Code, Division 2 (Healing Arts), to:

(a) submit a human biological specimen to a laboratory for a test to detect the presence of HIV, a component of HIV, or antibodies or antigens to HIV, and;

(b) receive laboratory test results. This includes designees who are persons authorized by, and acting under the general supervision of, a licensed physician and surgeon, or persons working in publicly-funded confidential counseling and testing programs acting under the general supervision of, and following the protocols approved by, the local Health Officer for the local health department.

Authority cited: Sections 100180, 100275, 101160, 120125 and 120130, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1241, 1281 and 1285, Business and Professions Code; Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(10) Adopt Section 2641.50 as follows:

Section 2641.50. Health Officer and Local Health Officer.

"Health Officer and Local Health Officer" means the officer appointed by the local governing body (county, city, and district), as defined in Section 2500.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(11) Adopt Section 2641.55 as follows:

Section 2641.55. HIV/AIDS Case Report.

"HIV/AIDS Case Report" means California Department of Health Services HIV/AIDS Confidential Case Report form, Adult (DHS 2001A, revised January 2001) or Pediatric (DHS 2001B, revised January 2001), hereby incorporated by reference in this Article and available from the local health department or the Department.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(12) Adopt Section 2641.60 as follows:

Section 2641.60. Laboratory.

"Laboratory" means a 'clinical laboratory,' a 'physician office laboratory,' or a 'public health laboratory,' as defined in Business and Professions Code, Section 1206, that is authorized to perform clinical laboratory tests or examinations in California or on a specimen originating in California.

Authority cited: Sections 1224 and 1288, Business and Professions Code; Sections 100180, 100275, 101160, 120125 and 120130, Health and Safety Code.

Reference: Sections 1206, 1220, 1265 and 1281, Business and Professions Code.

(13) Adopt Section 2641.65 as follows:

Section 2641.65. Laboratory Test.

"Laboratory test" means clinical laboratory test or examination as defined in Business and Professions Code, Section 1206 (a) (4) and performed by a laboratory as defined in this Article.

Authority: Sections 1224 and 1288, Business and Professions Code; Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 1202.5 and 1206, Business and Professions Code; Section 101160, Health and Safety Code.

(14) Adopt Section 2641.70 as follows:

Section 2641.70. Local Health Department.

"Local health department" means the governing body providing public health services to cities and/or counties, as identified in Health and Safety Code, Section 101185.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(15) Adopt Section 2641.75 as follows:

Section 2641.75. Non-Name Code.

"Non-name code" means a designation required by Section 2645 of this Article, that does not readily identify an HIV-infected individual.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(16) Adopt Section 2641.80 as follows:

Section 2641.80. Personal Information.

"Personal information" means an individual's complete Social Security Number, complete surname, home address, electronic mail address or telephone number.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(17) Adopt Section 2641.85 as follows:

Section 2641.85. Publicly-Funded Confidential Counseling and Testing Program.

"Publicly-funded Confidential Counseling and Testing Program" means a program financed by federal, state or local governmental agencies that provides confidential HIV tests to patients.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(18) Adopt Section 2641.90 as follows:

Section 2641.90. Soundex Code.

"Soundex code" means a phonetic, alphanumerical formula which is used to convert the first letter and sequential consonants of an individual's surname into a symbol; identified by the Department as form DHS 2001SC (3/01), and hereby incorporated by reference in this Article.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

Sub-Article 4. Reporting Requirements

(19) Adopt Section 2643.5 as follows:

Section 2643.5. HIV Reporting by Health Care Providers.

(a) Each health care provider that orders a laboratory test used to identify HIV, a component of HIV, or antibodies or antigens to HIV shall submit the following to the laboratory performing the test:

(1) A pre-printed laboratory requisition form which includes all documentation as specified in 42 CRF 493.1105 (57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19. 1993) and adopted in Business and Professions Code, Section 1220, or;

(2) A completed Department of Health Services Confidential Counseling and Testing Program laboratory requisition form DHS 8257A (3/01), hereby incorporated by reference in this Article.

(b) The person authorized to order the laboratory test shall provide the following information to the laboratory:

(1) First and third letters of patient's last name or DHS client number; and

(2) Patient gender (male, female, transgender male-to-female, or transgender female-to-male); and

(3) Patient date of birth (month, day, year); and

(4) Date biological specimen was collected; and

(5) Name, address, telephone number of the health care provider, the facility where services were rendered; and if applicable:

(6) Indication of the patient's choice for "confidential" or "anonymous" HIV testing.

(c) Each health care provider shall, within seven calendar days of receipt of a patient's confirmed HIV test from a laboratory, report the confirmed HIV test to the local Health Officer for the jurisdiction where the health care provider facility is located. The report shall consist of a completed copy of the HIV/AIDS Case Report form.

(d) HIV reporting by non-name code to the local Health Officer, via submission of the HIV/AIDS Case Report, shall not supplant the reporting requirements in Article 1 of this Subchapter when a patient's medical condition progresses from HIV infection to an Acquired Immunodeficiency Syndrome (AIDS) diagnosis.

(e) When reporting a confirmed HIV test, a health care provider shall not release a patient's personal information to the local Health Officer except for patients whose clinical conditions meet the AIDS reporting criteria, as specified in Article 1 of this Subchapter.

(f) A health care provider who receives notification from an out-of-state laboratory of a confirmed HIV test for a California patient shall report the findings to the local Health Officer for the jurisdiction where the health care provider facility is located.

(g) Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the health care provider except as authorized by this Article, other state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of that individual.

(h) When a health care provider orders multiple HIV-related viral load tests for a patient, or receives multiple laboratory reports of a confirmed HIV test, the health care

provider shall be required to submit only one HIV/AIDS Case Report, per patient, to the local Health Officer.

Authority cited: Sections 100180, 100275, 120125, 120130 and 120140, Health and Safety Code.

Reference: Sections 1202.5, 1206, 1206.5, 1220, 1241, 1265 and 1281, Business and Professions Code; Sections 100180, 101160, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(20) Adopt Section 2643.10 as follows:

Section 2643.10. HIV Reporting by Laboratories.

(a) The laboratory director, or authorized designee shall, within seven calendar days of determining a confirmed HIV test, report the confirmed HIV test to the Health Officer of the local health jurisdiction where the health care provider facility is located. The report shall include the:

(1) First and third letters of the patient's last name or DHS client number; and

(2) Patient gender (male, female, transgender male-to-female, or transgender female-to-male); and

(3) Patient complete date of birth; and

(4) Name, address, and telephone number of the health care provider and facility that submitted the biological specimen to the laboratory; and

(5) Name, address, and telephone number of the laboratory; and

(6) Laboratory report number as assigned by the laboratory; and

(7) Laboratory results of the test performed; and

(8) Date the biological specimen was tested in the laboratory.

(b) A laboratory shall not transmit a patient's personal information to the local health department.

(c) A laboratory that receives incomplete patient data from a health care provider for a biological specimen with a confirmed HIV test, shall contact the submitting health care provider to obtain the information required pursuant to (a) (1)–(4) of this Section prior to reporting the confirmed HIV test to the local Health Officer.

(d) A laboratory shall include the test requisition form when transferring a biological specimen to another laboratory for testing. The laboratory that first receives the biological specimen from the health care provider shall report confirmed HIV tests to the local Health Officer.

(e) Laboratories shall not be required to submit reports to the local health department for confirmed HIV tests for patients of an Alternative Testing Site or other anonymous HIV testing program, a blood bank, or for participants of a blinded and/or unlinked seroprevalence study.

(f) When a California laboratory receives a biological specimen for testing from an out-of-state laboratory or health care provider, the California director of the laboratory shall ensure that a confirmed HIV test is reported to the state health department in the state where the biological specimen originated.

(g) Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the laboratory except as authorized by this Article, other state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of the individual.

Authority cited: Sections 1224, Business and Professions Code; Sections 100180, 100275, 120125, 120130 and 120140, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1209, 1220, 1241, 1265, 1281 and 1288, Business and Professions Code; Sections 100180, 101150, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(21) Adopt Section 2643.15 as follows:

Section 2643.15 HIV Reporting by Local Health Officers.

(a) The local Health Officer or his or her authorized designee shall match and unduplicate laboratory reports of confirmed HIV tests with the local health department HIV/AIDS registry database and with HIV/AIDS Case Reports received from health care providers and not entered into the database.

(b) The Health Officer or his or her authorized designee shall, within 45 calendar days of receipt of a laboratory report of a confirmed HIV test, submit unduplicated HIV/AIDS Case Reports to the Department.

(1) HIV/AIDS Case Reports shall be sent by courier or mail to California Department of Health Services, Office of AIDS, HIV/AIDS Case Registry.

(2) The local Health Officer or his or her authorized designee shall not report confirmed HIV tests for patients of an Alternative Testing Site or other anonymous counseling and testing program, a blood bank, or for participants of a blinded and/or unlinked HIV seroprevalence study.

(c) The local Health Officer or his or her authorized designee shall retain in the local health department HIV/AIDS registry a HIV/AIDS Case Report for an infant under the age of 18 months until the infant's HIV infection is confirmed.

(d) Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the local Health Officer or his or her authorized designee except as authorized by this Article, other state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of the individual.

Authority cited: Sections 100180, 100275, 120125, 120130 and 120140, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(22) Adopt Section 2643.20 as follows:

Section 2643.20. HIV Reporting Exemptions.

Alternative Testing Sites; other anonymous or unlinked HIV testing programs; blood banks; and blinded and/or unlinked seroprevalence studies are exempt from this HIV reporting regulation.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

Sub-Article 6. Non-Name Code

(23) Adopt Section 2645 as follows:

Section 2645. Components of the Non-Name Code.

The health care provider shall create a non-name code for each patient with a confirmed HIV test who has not received an AIDS diagnosis. Components of the non-name code shall consist of an individual's:

(a) Soundex code; and

(b) Complete date of birth (2-digit month, 2-digit day, 4-digit year); and

(c) Gender (male [1], female [2], transgender male-to-female [3], or transgender female-to-male [4]); and

(d) Last four digits of the Social Security Number (if not available, use four digits of zero).

Authority cited: Sections 100180, 100275, 120125, 120130 and 120140, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.